United States Public Health Service
Technology Transfer Manual
Chapter No. 607

NIH Policy and Procedures on Determinations of Exceptional Circumstances
Under NIH Grants, Contracts, and Cooperative Agreements

A. PURPOSE

This Manual Chapter sets forth NIH policy and procedures for making a determination under 37 C.F.R. § 401.3 that exceptional circumstances exist to warrant deviation from standard patent rights clauses in a particular grant, contract, or cooperative agreement.

B. BACKGROUND

The Bayh-Dole Act provides the statutory basis for federal technology transfer activities, including the patenting and licensing of federally funded inventions by recipient organizations. The Act permits recipients of federal funds to elect title to subject inventions that arise from the use of those funds. If recipients elect title, the Act requires them to file patent applications, seek commercialization opportunities, and report back to the funding agency on efforts to obtain utilization of their inventions.

The Bayh-Dole Act gives NIH authority either to restrict the recipient's right to elect title, or to retain title itself, to subject inventions in the terms of a funding agreement, in exceptional circumstances. Specifically, the Act provides:

> Each nonprofit organization or small business firm may, within a reasonable time after disclosure . . . elect to retain title to any subject invention: *Provided, however*, that a funding agreement may provide otherwise . . . in exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of [the Act].

35 U.S.C. § 202(a). These objectives, as set forth in the language of the statute, are

> to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research or development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against non-use or unreasonable use of inventions; and to minimize the costs of

administering policies in this area.

35 U.S.C. § 202. Regulations implementing the exceptional circumstances provisions of the Bayh-Dole Act are at 37 C.F.R. Part 401.3.

C. POLICY

It is the policy of the NIH to comply with the letter and spirit of the Bayh-Dole Act in implementing its authority to restrict or eliminate a funding recipient's right to elect title to subject inventions in the terms of a funding agreement. NIH presumes that the policy and objectives of the Bayh-Dole Act are generally best served by implementing the standard patent rights clauses in grants, contracts, and cooperative agreements. The Bayh-Dole Act has been successfully implemented by the widespread election of title to subject inventions by government grantees and contractors, and the subsequent commercialization efforts of those grantees and contractors.

In limited circumstances, a determination of exceptional circumstances (DEC), with the resulting restriction or elimination of recipients' rights to elect title to subject inventions, is the only means of achieving an important programmatic interest. In such cases, a DEC is appropriate upon a finding by the Director, NIH, that such restriction or elimination will better promote the policy and objectives of the Act. It is the policy of the NIH that DECs be made on a case-by-case basis, after consideration of other alternatives, and with appropriate management controls and review as set forth in this Chapter. Alternative patent rights clauses implemented under DECs should be narrowly tailored and, to the extent practicable, provide for: 1) recipient retention of rights outside the scope of the DEC; 2) recipient retention of rights to research uses of subject inventions, where appropriate; 3) recipient retention of the ability to petition the agency for greater intellectual property rights in particular subject inventions within the scope of the DEC; and, 4) publication of the research results by the funding recipient investigators, consistent with NIH policies.

DECs are considered and made in accordance with the Federal Acquisition Regulation (FAR), Subpart 27.3, for contracts and 37 CFR Part 401 for grants and cooperative agreements.

D. PROCEDURES

1. Program, grants, or contracting officials of NIH Institutes and Centers (ICs) and the IC Technology Development Coordinator (TDC) should consult with each other early in the grant or acquisition cycle whenever a deviation to the standard patent rights clause is contemplated. In consultation with the Office of the General Counsel (OGC), Office of Technology Transfer (OTT), NIH Office of Contracts Management (if a contract) or Office of Policy for Extramural Research Administration (OPERA) (if a grant or cooperative agreement), the IC TDC or other designated official will advise IC officials and assist the IC in deciding whether to recommend to the Director, NIH that a DEC is appropriate and justified.

2. The following questions should be considered by the IC in deciding whether to recommend a DEC. Responses, explanations, and supporting rationale will be considered by the Director, NIH in making a DEC.

    a. Is the funding agreement a contract, grant, or cooperative agreement? Generally, DECs may be considered more appropriate for contracts, since contracts are for the direct benefit and use of the government, and involve a higher degree of agency control than grants or cooperative agreements.

    b. Why is a deviation to the standard patent rights clause considered essential to achieve programmatic objectives? What alternative means of achieving program objectives have been considered?

    c. Have interested parties been provided notice and their responses, if any, considered?

    d. Why will a DEC better promote the policy and objectives of the Bayh-Dole Act and implementing regulations?

    e. Is the proposed DEC as narrowly tailored as possible to achieve the articulated programmatic objective?

    f. Does the proposed DEC provide for the funding recipient(s) to retain rights to subject inventions (in their entirety or by fields of use) that are unrelated to or outside the scope of the DEC and its programmatic objective?

    g. Where appropriate, does the proposed DEC provide for the funding recipient(s) to retain or request rights to research uses of subject inventions (in their entirety or by fields of use) that are within the scope of the DEC?

    h. Does the proposed DEC provide the funding recipient(s) with the ability to request greater rights (see 37 C.F.R. § 401.3(b)) to any subject invention within the scope of the DEC for which the funding recipient can achieve the programmatic objective?

3. If the IC wishes to recommend to the Director, NIH that a DEC be made and implemented, the IC will forward a proposed DEC and recommendation memorandum to the NIH Office of Contracts Management (if a contract) or OPERA (if a grant or cooperative agreement), which will receive it on behalf of the Director, NIH. The memorandum should contain a discussion of the factors identified above, and be prepared in a manner as to serve as the agency's administrative record of deliberation on and justification for the DEC.

4. DECs will undergo Office of the Director (OD) review on behalf of the Director, NIH. The Office of Contracts Management or OPERA will review and clear the IC recommendation and proposed DEC as well as coordinate the review and clearance by the Office of the Deputy Director for Extramural Research, the Office of Technology

Transfer, and the Office of the General Counsel. Each OD office may review and clear (with or without comment)s or object to the proposed DEC, and may request a meeting to discuss significant issues.

5. The Office of Contracts Management or OPERA will forward the proposed DEC, IC recommendation memorandum, and the OD clearances, comments, or objections to the Director, NIH for a determination.

E. ALTERNATIVES TO DECs

NIH views the use of the exceptional circumstances authority to be appropriate where there is no lesser means of achieving an important programmatic goal, consistent with the policies and objectives of the Bayh-Dole Act. NIH encourages ICs and proposed recipients of IC funds to explore alternative means of achieving programmatic goals in lieu of DECs. NIH has been very successful in the past in avoiding DECs by discussing programmatic goals with known or anticipated funding recipients and agreeing on mutually beneficial terms and conditions.

Examples of alternatives to some DECs include: 1) recipient-generated data sharing plans; 2) advance establishment of agreements between proposed funding recipients and third party providers of materials for the funded project (e.g., license option agreement for the provider); 3) three-party Cooperative Research and Development Agreements (CRADAs) between the proposed recipient, third party provider of materials and IC; and, 4) within cooperative agreements, advance agreement to allow joint steering committees to make intellectual property decisions.

F. EFFECTIVE DATE

The policy and procedures set forth in this Manual Chapter are effective immediately upon issuance. All previous procedures are superseded. This Manual Chapter is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any other persons.

G. ADDITIONAL INFORMATION

For more information on this Manual Chapter, contact the Office of Technology Transfer, NIH, (301) 496-7057, or the appropriate representative of OCM, OGC, and OPERA.